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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,679	03/18/2004	Andrew D. Sutton	263742002802	8165
25226 7590 11/28/2007 MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER GEORGE, KONATA M	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/804,679

Applicant(s)

SUTTON ET AL.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20,22-24 and 26-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20,22-24 and 26-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 20, 22-24 and 26-44 are pending in this application.

#### ***Request for Continued Examination (RCE)***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

#### ***Action Summary***

The rejection of claims 20, 22-24 and 26-43 under 35 U.S.C. 103(a) as being unpatentable over Platz et al. is being maintained for the reasons stated in the office action dated September 28, 2007.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 20, 22-24 and 26-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al. (US 6,509,006).

Applicant claims a composition comprising dry, discrete microparticles which comprise a water-soluble carrier, and an effective amount of a therapeutic agent, wherein the agent is a substantially non-denatured protein, peptide, or enzyme.

***Determination of the scope and content of the prior art***  
**(MPEP §2141.01)**

Platz et al. disclose a pharmaceutical-based dry powder composition for pulmonary delivery, wherein the composition comprises a therapeutically effective amount of a pharmaceutical in combination with a pharmaceutically acceptable carrier (col. 5, lines 63-67). Column 8 line 67 through column 9, line 7 teach the preferred particle size as being less than 10 microns. Column 6, lines 1-13 teach the pharmaceutical as a protein, peptide or enzyme. Column 6, lines 27-34 teach the carrier in amounts from 0.05% to 99.5%. Column 6, lines 35-67 through column 7, line 6 teach the carrier as an excipient, such as, bulking agents for example carbohydrates,

polysaccharides, mannitol, etc. Column 7, lines 27-56 teach a dry powder inhaler for the composition. Column 7, lines 7-11 teach the addition of additives the can improve dispersibility of the powder.

***Ascertainment of the difference between the prior art and the claims***  
**(MPEP §2141.02)**

Platz et al. do not teach the protein being substantially non-denatured.

***Finding of prima facie obviousness***  
***Rational and Motivation (MPEP §2142-2143)***

It is the position of the examiner that although substantially non-denatured proteins, peptides or enzymes are not explicitly taught by Platz et al., it can be inferred from the reference that it can be used. As mentioned above, column 6, lines 1-13 teach pharmaceuticals such as proteins, peptides or enzymes can be employed in the composition. The recitation of proteins by Platz et al. is broad and can encompass all types of proteins, including denatured proteins, peptides or enzymes as claimed by applicant. Therefore, the invention of Platz et al. would have been obvious to one of ordinary skill in the art.

### ***Response to Arguments***

Applicant's arguments filed October 31, 2007 have been fully considered but they are not persuasive. Applicant has amended the claims to recite that the microparticles are "produced by a process which is controlled to avoid denaturing of the protein, peptide or enzyme". This amendment does not overcome the prior art. Although it is not mentioned by the prior art of a process by which the microparticles are made, it would have been obvious to one of ordinary skill in the art to make the microparticles in a manner that would not denature the protein, peptide or enzyme. A denatured protein, peptide or enzyme would have no physiological function and would be useless. Furthermore, where claims are directed to a composition, the manner by which the individual components are made is not a patentable distinction if the resulting composition is the same as taught in the prior art. The claim is to a composition and not a method of making the composition. Therefore, any method of making the microparticles would have been obvious to one of ordinary skill in the art at the time of the invention.

### ***Conclusion***

Claims 20, 22-24 and 26-44 are rejected.

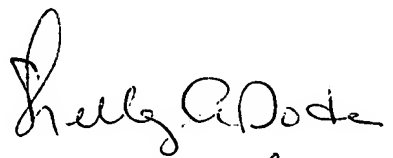
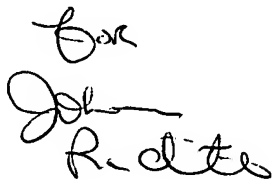
***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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